K061570

JUL - 3 2006

SUMMARY

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
ASPIRATION NEEDLE

Regulatory Affairs Contact:	Muhamad Ansari Busse Hospital Disposables PO Box: 11067 75 Arkay Dr. Hauppauge NY 11788
Telephone:	631-435-4711 Ext: 254
Fax:	631-435-2849
Date Summary prepared:	May 31, 2006
Product Trade Name:	I-Style Bone Marrow Aspiration Needle
Common Name:	Bone Marrow Biopsy Aspiration Needle.
Classification:	Class II, 21 CFR 868.5150
Product Code:	KNW
Predicate Device:	Manan Bone Marrow Aspiration Needle
Device Description:	The I-Style Bone Marrow Aspiration Needle consists of an 8ga – 15ga needle and a triple sharpened atraumatic tip stylet of corresponding size. The needle is manufactured in lengths upto 2" with an adjustable depth stopper and graduated scale which allow for the adjustment of the penetration length of the needle. A luer lock connection is provided in the molded needle handle to allow aspiration of bone marrow or blood by use of a standard surgical syringe. The needle will be provided as sterile, single use, disposable device. They will be packaged individually or included in Bone Marrow Biopsy Tray.

Intended Use:	The I-Style Bone Marrow Aspiration Needle is to be used for the aspiration of bone marrow.

510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Summary of Testing:	All materials used in the fabrication of the specialty needles were evaluated through biological qualification safety tests. The biocompatibility tests performed were L929 Men Elution Test, Kligman Maximization Test, Intracutaneous Injection Test, Systemic Injection Test, Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay These materials have met the testing requirements and were found to be acceptable for the intended use. Summary of tests performed to prove the substantial equivalence of the Aspiration Needles with the predicate device: 1. Same intended use 2. Same flow rate 3. Same bonding strength
Technological Characteristics: [21 CFR 807.92(a)(6)]	The subject device has the same Technological Characteristics as a legally marketed predicate device.
Conclusion: [21 CFR 807.92(b)(3)]	The above statements are accurate representations of the device Busse intents to market. All data and information submitted in this premarket notification is truthful and accurate and no material fact has been omitted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 2006

Busse Hospital Disposables
% Mr. Muhamad Ansari
Director, Regulatory Affairs
P.O. Box 11067
Hauppauge, New York 11788-0920

Re: K061570
Trade/Device Name: I-Style Bone Marrow Aspiration Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: May 31, 2006
Received: June 6, 2006

Dear Mr. Ansari:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE

510(k) Number (if known): K061570

Device Name: I-Style Bone Marrow Aspiration Needle.

Indication for Use: The I-Style Bone Marrow Aspiration Needle is intended for Aspiration of Bone Marrow.

Prescription Use____x_____ (Per 21 CFR 801Subpart D) AND/OR Over-The-Counter Use_____ (Per 21 CFR 801Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061570